

REMARKS

I. Status of Claims

Claims 1-20 are pending. Claims 1, 8 and 15 are independent. Claims 1 and 15 have been amended to correct typographical errors. New claims 21-25 have been added to provide a more complete scope of protection for the invention.

Claims 1-7 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,867,821 to Ballantyne et al (hereinafter "Ballantyne et al") in view of U.S. Patent No. 6,283,761 to Joao (hereinafter "Joao"), and further in view of U.S. Patent No. 5,937,387, to Summerell et al (hereinafter "Summerell et al"). Claims 8-14 are rejected under 35 U.S.C. § 103(a) as being obvious over Ballantyne et al and Joao in view of U.S. Patent No. 5,557,514, to Seare et al (hereinafter "Seare et al"). Claims 15-20 are rejected under 35 U.S.C. § 103(a) as being obvious over Ballantyne et al and Joao in view of U.S. Patent No. 5,319,355 to Russek (hereinafter "Russek") and further in view of U.S. Published Application No. 2003/0055679, to Soll et al (hereinafter "Soll et al").

II. Rejections Under 35 U.S.C. § 103(a)

A. Claims 1-7

In the Office Action, Summerell et al is relied on to purportedly teach the following claim 1 recitation:

"said remote monitoring stations being configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of a selected one of said treatment programs into the patient's lifestyle comprising at least one of questions concerning health or treatment and responses to questions concerning health or treatment that are generated using said electronic self-management tools;"

and Joao is relied on to purportedly teach the following claim 1 recitation:

“said computer network being configured with electronic assessment tools to allow a health care provider to assess said patient health-related data to determine progress of the patient on the selected treatment program and whether information relating to the selected treatment program needs to be conveyed to the patient.”

Applicants respectfully submit that Summerell et al teaches away and therefore does not render the claimed invention obvious since a person of ordinary skill, upon reading this reference, would be led in a direction divergent from the path taken by the Applicants. Claim 1 recites, among other limitations:

(1) a system that comprises a computer network having a database for storing “accumulated health-related data pertaining to health-related conditions and treatment;”

(2) the computer network is “adapted to receive said patient health-related data from said remote monitoring stations, [and] *to establish treatment programs* (emphasis added) for said patients *based on* their respective patient health-related data and said accumulated health-related data;”

(3) remote monitoring stations that are “configured with electronic self-management tools for receiving from a respective patient said patient health-related data relating to integration of *a selected one of said treatment programs* (emphasis added) into the patient’s lifestyle;” and

(4) electronic assessment tools that “allow a health care provider to assess said patient health-related data to determine progress of the patient on *the selected treatment program* and whether information relating to the selected treatment program needs to be conveyed to the patient.”

On the other hand, Summerell et al disclose a PC-based system for providing individuals with a customized wellness plan whereby a predetermined set of health-related data can be entered by an individual (i.e., a patient) and used to automatically calculate that individual’s physiological age based on a predetermined set of wellness factors. In other

words, Summerell et al seeks to provide a tool for users to select their own wellness plan without involvement of a health care provider.

Applicants therefore respectfully submit that it would have been unlikely for a person of ordinary skill at the time of the invention to read Summerell et al and find the line of development flowing from its disclosure to be productive of the results sought by the claimed invention (e.g., a system that accumulates health-related data pertaining to treatment, establishes treatment programs for patients, allows a patient to provide data relating to "integration of a selected one" of these treatment programs, and allows a health care provider to assess and determine progress of the patient "on the selected treatment program," among other results). First, Summerell et al is silent regarding storage of data pertaining to treatment and the establishment of treatment programs, as well as regarding the electronic assessment tools of health care providers, as recited in claim 1. Second, Summerell et al states as an objective "a system the counsels individuals in a meaningful way to adopt and maintain healthy behaviors" (see column 2, lines 56-69). Also, Summerell et al cites a number of patents in its background section that are "generally directed toward diagnostic purposes, and are for use by medical professionals" (see column 2, lines 14-16). Thus, according to its objective and unlike the prior art it cites, Summerell et al seeks to provide a tool for users to select their own wellness plan without involvement of a health care provider. See also Fig. 1 in which only a user 100 is displayed, and Figs. 18-25 which indicate "*Consult your doctor before starting and Wellness plan.". The screens in Figs. 26-29 provide recommendations automatically selected from a predetermined set of recommendations based on user data and their calculated physiological age, and therefore do not involve assessment of progress on a selected treatment program or determination of conveyance of information relating to that treatment program by a health care provider, as recited in claim 1.

The Office Action relies on column 2, lines 56-69 of Summerell et al to purportedly provide motivation to combine the teachings of Summerell et al with the combined teachings of Ballantyne et al and Joao. As stated above, column 2, lines 56-69 of Summerell et al, however, states that it is an object of the invention disclosed in Summerell et al to provide a

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system that counsels *individuals* (emphasis added) to adopt and maintain healthy behaviors, and therefore not provide information from patients' self-health management tools to *health care providers* to allow *health care providers* to assess patient health-related data to determine progress of the patient on a treatment program and whether information pertaining to the treatment program needs to be conveyed to the patient.

Column 5, lines 64-67 of Summerell et al discuss the disclosed system analyzing "patient data according to guidelines to determine suitable courses of action." This text must not be taken out of context and assumed to teach treatment as claimed. A careful reading of Summerell et al provides for assessment of a user's "relative wellness for a set of relative risk factors" described in column 9, lines 37-60 using statistical analysis (see column 11, line 44 through column 16, lines 35 and Figs. 7-14). Predetermined recommendations are then made automatically by the individual's PC (see Figs. 26-29). Further, column 6, lines 11-13 of Summerell et al discuss using the disclosed system by a primary care practice to track a patient's progress toward an improved level of wellness. Again, text must not be taken out of context and assumed to teach treatment as claimed. The level of wellness is merely measured from the statistical factors described in the text of Summerell et al, and no description is made regarding storing data relating to treatment programs, or selecting a treatment program. Progress toward wellness is merely monitored in Summerell et al.

While the master library (ML) in Ballantyne et al can store post-recovery rehabilitation information (see column 11, lines 15-18), it is otherwise silent as to how a treatment program is established or selected for a patient, or whether a patient is making progress on the treatment program. The Office Action relies on Joao to purportedly teach the electronic assessment tools as claimed. Even if Joao could arguably be interpreted as disclosing selection of a treatment program and determination that a treatment/procedure is performed in the patient, the disclosed evaluation report is transmitted to the payer (see column 28, lines 49-60) and not to the patient. By contrast, claim 1 recites conveying information relating to a selected treatment plan to the patient.

In view of the foregoing, Applicants respectfully submit that impermissible hindsight reconstruction was used to pick and choose among the cited references' purported disclosures

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to render claim 1 obvious using Applicant's claimed invention as a guide. Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 1-7 is respectfully requested.

B. Claims 8-14

In the Office Action, Seare et al is relied on to purportedly teach the following claim recitations:

*"receiving economic data relating to protocols used in said treatment programs;
aggregating said patient health-related data, said clinical data and said economic data with information comprising population outcomes and generic standards of care; and
determining from said aggregated data recommendations for improving the treatment programs."*

Seare et al teaches "converting raw medical providers billing data into an informative historical database" (see column 4, lines 34-36) to provide a mechanism for assessing medical services utilization patterns of medical providers and thereby generating statistically-generated medical provider utilization profiles.

Applicants respectfully submit, for reasons stated above, that Ballantyne does not disclose a computer network for establishing treatment programs for said patients based on their respective patient health-related data and accumulated health-related data, as recited in claim 8. Seare et al does not overcome this deficiency and therefore does not teach or suggest receiving economic data relating to protocols used in these treatment programs.

In addition, Seare et al does not disclose or suggest aggregating population outcomes and generic standards of care with other data, as recited in claim 8. Joao is relied on in the Office Action to purportedly teach the recited clinical data comprising outcomes of the treatment programs established by the claimed computer network. Applicants respectfully submit that, while Joao briefly mentions treatment monitoring and evaluation of treatment progress, Joao does not disclose generating clinical data comprising outcomes of treatment programs.

Seare et al uses historical medical provider billings to statistically establish utilization profiles. As indicated in Fig. 4 of Seare et al, a medical provider diagnosis indicated in the billing data can have one of three outcomes, that is, resolution, return to chronic disease state, or complication of the disease. If Seare et al can provide outcome information from medical provider billing data that may arguably teach clinical data as claimed, then such outcome data cannot be population outcome information as claimed.

Further, since the outcomes in Fig. 4 of Seare et al are only available from the raw billing data, they are not population outcomes as claimed. Seare et al uses CPT and other codes for reporting a medical service (see column 6, lines 7-9) and different tables to determine episodes of care to be included in the analysis and creation of a utilization profile for a medical provider. One table provides a numerical factor to adjust the frequency of a code based on age or gender in determining the provider's profile. This, however, only relates to that providers' medical services as evidenced in his billing records and not to outcomes of a population aggregated with the outcomes of medical services provided by that medical provider.

Since Seare et al does not overcome the deficiencies of Ballantyne et al and Joao, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 8-14 is respectfully requested.

C. Claims 15-20

In the Office Action, Soll et al is relied on to purportedly teach the following claim 15 recitation, among others:

"receiving a plan of care initiated by the corresponding one of the healthcare managers assigned to the patient as a result of an interview with the patient and the assessment, the plan of care being used in the establishment of the treatment program for the patient."

In Soll et al, the interview in paragraph [0058] thereof and relied on in the Office Action refers to patient exit and revisit interviews to assess response to treatment. Nothing in Soll et al discloses or suggests receiving a plan of care as a result of an interview for use in

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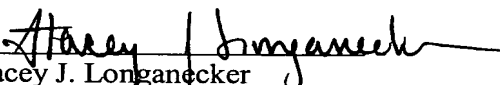
the establishment of a treatment program. Further, for reasons stated above in connection with claims 1-7, Ballantyne et al does not disclose a establishing a treatment program for respective patients based on their respective patient health-related data and accumulated data relating to health-related conditions and treatments. In addition, neither Soll et al, Joao, nor Russek overcome the deficiencies of Ballantyne et al, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 15-20 is respectfully requested.

III. Conclusion

Accordingly, withdrawal of 35 U.S.C. § 103(a) rejections of the claims 1-20 is respectfully requested.

In view of the above, it is believed that the application is in condition for allowance, including claims 1-25, and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the telephone number indicated below.

Respectfully submitted,


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